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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,164	03/27/2002	Patrick Chaton	220681USOXPCT	9801
22850	7590	01/13/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER

1634

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,164

Applicant(s)

CHATON ET AL.

Examiner

Jeffrey Fredman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 15-39 been renumbered 14-38. The highest previously present claim had been claim 13, not claim 14.

Claim Interpretation

2. The claims are drawn to methods which expressly indicate the phrase "without labeling". However, this term is not defined. Therefore, when the second compound used in the recognition reaction is an intercalator such as Ethidium bromide or Acridine Orange, the claims as properly interpreted do not distinguish these second compounds since they are not labeled with any exogenous molecule. Therefore, methods using these elements that are unlabeled meet this requirement of "without labeling" of the claims.

Claim Rejections - 35 USC § 112/101

3. Claims 31, 32 and 38 provides for the use of a method for detection, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 31, 32 and 38 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 14, 16, 18, 20, 22, 24, 25, 26, 28, 31, 32 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Adelhelm et al (SPIE (1996) 2629:325-332).

Adelhelm teaches a method of detection (see abstract) comprising:

- a) contacting the nucleic acid with a solution to be tested comprising the interacting intercalator dye (see page 328),
- b) fixing a first nucleic acid on a solid support (see page 328),
- c) measuring the absorption of the sample by a photothermal method (see page 329, figures 5 and 6, for example).

With regard to claim 16, Adelhelm teaches the use of a thermal lens method (see page 326, figure 1).

With regard to claim 18, Adelhelm teaches a photothermal method in which the sample is illuminated by a He-Ne probe beam and absorption is detected by refraction and reflection of the probe beam (See page 327-328).

With regard to claim 20, Adelhelm teaches the use of interferometry (see page 327).

With regard to claim 22, Adelhelm teaches a transvers configuration (see figure 4).

With regard to claim 24, Adelhelm teaches the use of a pulsed Argon laser (see figure 4).

With regard to claim 25 and 26, Adelhelm teaches the use of a multielement photodiode (see figure 4).

With regard to claim 28, Adelhelm teaches a probe beam that is not absorbed by the substrate or molecules (see figure 2).

With regard to claims 31, 32 and 38, Adelhelm teaches detection of doublestranded nucleic acids which detects whether they are hybridized to one another (see page 328).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 14-26, 28, 30-35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adelhelm in view of Ida (WO 00/20861 (April 13, 2000)).

Adelhelm teaches a method of detection (see abstract) comprising:

- a) contacting the nucleic acid with a solution to be tested comprising the interacting intercalator dye (see page 328),
- b) fixing a first nucleic acid on a solid support (see page 328),
- c) measuring the absorption of the sample by a photothermal method (see page 329, figures 5 and 6, for example).

With regard to claim 16 and 17, Adelhelm teaches the use of a thermal lens method (see page 326, figure 1).

With regard to claim 18 and 19, Adelhelm teaches a photothermal method in which the sample is illuminated by a He-Ne probe beam and absorption is detected by refraction and reflection of the probe beam (See page 327-328).

With regard to claim 20 and 21, Adelhelm teaches the use of interferometry (see page 327).

With regard to claim 22 and 23, Adelhelm teaches a transvers configuration (see figure 4).

With regard to claim 24, 33, 35, Adelhelm teaches the use of a pulsed Argon laser (see figure 4).

With regard to claim 25, 26, 34, Adelhelm teaches the use of a multielement photodiode (see figure 4).

With regard to claim 28, 37, Adelhelm teaches a probe beam that is not absorbed by the substrate or molecules (see figure 2).

With regard to claims 31, 32 and 38, Adelhelm teaches detection of doublestranded nucleic acids which detects whether they are hybridized to one another (see page 328).

Adelhelm suggests detection of nucleic acid hybridization (see page 326) but indicates that labeling is required, which element is not permitted by the current claims.

Ida teaches detection of nucleic acid hybridization by photothermal detection where no label is present (see U.S. Patent 6,537,801, column 1, lines 39-48, for translation of WO 00/20861 page 2, lines 10-24). Ida further teaches the use of CCD device (see page 4, line18). Further, Ida expressly teaches the steps of claim 15 in which a nucleic acid is fixed to a solid support, contacted with a target second nucleic acid, washed and detected (see pages 3 and 4).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the photothermal method of Adelhelm for the detection of DNA hybridization without labels since Ida expressly teaches that the photothermal method such as that of Adelhelm can be used for such detection (see page 4, line 18). An ordinary practitioner would have been motivated to make this substitution since Ida expressly teaches that photothermal detection is a desirable equivalent in the detection of nucleic acids.

9. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

10. Claims 27, 29 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adelhelm in view of Ida (WO 00/20861 (April 13, 2000)) as applied to claims 14-26, 28, 30-35, 37 and 38 and further in view of Milofsky et al (Anal. Chem. (1993) 65:153-157).

Adelhelm in view of Ida teach the limitations of claims 14-26, 28, 30-35, 37 and 38 as discussed above. Adelhelm in view of Ida do not teach the use of a 275 nm Argon laser as opposed to other wavelengths for DNA detection.

Milofsky teaches that for native fluorescence of DNA, a 275 nm Argon laser is used to illuminate the DNA(see abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the photothermal method of Adelhelm in view of Ida for the detection of DNA hybridization without labels with the 275 nm Argon laser of

Milofsky since Ida expressly teaches detection without labels and Milofsky teaches that 275 nm lasers will induce fluorescence of DNA, which is well known to have a maximum absorbance at A260. An ordinary practitioner, motivated by Ida to perform the DNA hybridization using the photothermal method, would have been motivated to use an appropriate laser such as that of Milofsky, which is capable of illuminating the DNA without the use of labels. An ordinary practitioner would have been motivated to make this substitution since Milofsky expressly teaches that the Argon laser detection is a desirable equivalent in the detection of nucleic acids and is capable of an increase of 6 orders of magnitude in signal (see page 153, column 2).

11. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'Jeffrey Fredman', with a long, sweeping horizontal stroke extending to the right.

Jeffrey Fredman
Primary Examiner
Art Unit 1634